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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,251	02/14/2006	Sarah S. Bacus	PR60446USw	9708

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GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B475

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EXAMINER

AEDER, SEANE

ART UNIT

PAPER NUMBER

1642

NOTIFICATION DATE

DELIVERY MODE

02/28/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/568,251

**Applicant(s)**

BACUS ET AL.

**Examiner**

SEAN E. AEDER

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/86)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a method of treatment for an EGFR-expressing or erbB2-expressing solid tumor comprising determining the pre-treatment relative localization of pERK, administering a dual EGFR/erbB2 tyrosine kinase inhibitor, determining the relative localization of pERK after an initial period of treatment, wherein a shift in relative pERK localization from the nucleus to the cytoplasm indicates that a subject is more likely to exhibit a favorable clinical response to the treatment, as compared to a subject with no change in relative pERK localization.

Group II, claim(s) 10-18, drawn to a method to assess whether a subject with an EGFR-expressing or erbB2-expressing solid tumor is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor compound, comprising determining pre-treatment relative localization of pAKT, administering a dual EGFR/erbB2 tyrosine kinase inhibitor, determining the relative localization of pAKT after an initial period of treatment, where a shift in the relative pAKT localization from the nucleus to the cytoplasm indicates that the subject is more likely to exhibit a favorable clinical response to treatment with said therapeutic agent, compared to a subject with no change in relative pAKT localization.

Group III, claim(s) 19-25, drawn to a method to assess whether a subject with an EGFR-expressing or erbB2-expressing solid tumor is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor, comprising determining the pre-treatment relative localization of pERK in cells of said tumor, wherein an increased localization of pERK in the nucleus of tumor cells compared to localization in the cytoplasm indicates that the subject is not as likely to exhibit a favorable clinical response to said treatment, compared to a subject without increased nuclear localization of pERK.

Group IV, claim(s) 26-32, drawn to a method to assess whether a subject with an EGFR-expressing or erbB2-expressing solid tumor is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor, comprising

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determining the pre-treatment relative localization of pAKT in cells of said tumor, wherein an increased localization of pAKT in the nucleus of tumor cells compared to localization in the cytoplasm indicates that the subject is not as likely to exhibit a favorable clinical response to said treatment, compared to a subject without increased nuclear localization of pAKT.

Group V, claim(s) 33-38, drawn to a method to assess whether a subject with an EGFR-expressing or erbB2-expressing solid tumor is likely to exhibit a favorable clinical response to treatment with a dual EGFR/erbB2 tyrosine kinase inhibitor, comprising determining the pre-treatment level of ErbB2 in cells of said tumor, wherein an increased amounts of ErbB2 in tumor cells indicates that the subject is not as likely to exhibit a favorable clinical response to said treatment, compared to a subject with lesser amounts of ErbB2 in tumor cells.

The inventions listed as groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-V appears to be that they all relate to the special technical feature of administering dual EGFR/erbB2 tyrosine kinase inhibitors to subjects with EGFR-expressing or erbB2-expressing solid tumors.

However, Xia et al (Oncogene, September 2002, 21:6255-6263) teaches administering the dual EGFR/erbB2 tyrosine kinase inhibitor GW572016 to subjects with EGFR-expressing or erbB2-expressing solid tumors comprised of HN5 cells (see page 6259, in particular).

Therefore, the technical feature linking the inventions of groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner, Art Unit 1642